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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,603	SCHULZ ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,31 and 75-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,31 and 75-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' amendment filed on April 14, 2009, that includes a response to the non-final Office action dated September 19, 2008, has been entered. Claims 35, 53, and 58-67 have been amended, and claims 54 and 57 cancelled. Claims 68-71 were newly added. Accordingly, claims 35, 36, 43-49, 51-53 and 58-71 are pending in the Application and currently under examination.

Claims 1, 4-7, 31 and 77-79 have been amended and claims 8, 9, 80 and 81 cancelled. No claims were newly added. Accordingly, claims 1, 2, 4-7, 31 and 75-79 are pending in the application and currently under examination.

Withdrawn Objection to the Specification-Title

The title of the invention was objected to in the previous Office action dated September 19, 2009. Applicants have provided a new title that is of the invention to which the claims are directed. Thus, the objection is hereby withdrawn.

New Claim Rejections - 35 USC § 112- Second Paragraph

Claims 1, 2, 4-9, 31 and 75-81 were newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite, in the previous Office action dated September 19, 2009. Applicants' cancellation of claims 8, 9, 80 and 81 renders their rejection moot. Applicants have amended base claims 1 and 31 to indicate that the cells expressing said markers are the majority of cells, obviating the ground of rejection. Thus, the rejection is hereby withdrawn.

Maintained Claim Rejections - 35 USC § 112- New Matter

Claims 1, 2, 4-7, 31 and 75-79 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and introducing new matter. Applicants' cancellation of claims 8, 9, 80 and 81 renders their rejection moot. The rejection set

forth on pp. 3-4 of the previous Office action dated September 19, 2009 is maintained for reasons of record. The rejection has been reiterated as follows:

Base claim 1 and 31 recite human aneuploid embryonic stem cell cultures, wherein a majority of cells have an abnormal karyotype and wherein the cells of the culture do not express SSEA1, but express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin substantially uniformly.

Applicants state that no new matter has been presented in the amendment. Such is not found persuasive, because the specification fails to disclose either explicitly or implicitly, the characterization of any aneuploid embryonic stem cells cultured to express the combination of cell surface markers, either with a specific combination of chromosomal abnormalities, or as a majority of cells, as claimed. Example 11 of the instant specification discloses that sorted HESCs were positive for the combination of SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin; and negative for SSEA1 (paragraph [0176], p. 65). Example 19 describes various abnormal karyotypes for hESC BG01-derived cell lines, that include trisomies 1, 7, 8, 12, 14 and 17 and other mixed karyotypes (paragraph [0212], p. 78). However, the instant specification is silent on which specific autosomal abnormality corresponds to the specific combination of markers claimed. The specification is therefore silent on establishing a clear nexus between a particular karyotypic aneuploidy and the expression pattern of the cell surface markers claimed.

Thus, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of any of numerous human aneuploid stem cells that regardless of their karyotypic abnormality, express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin, either as an individual cell line or as a majority of cells in a mixed stem cell culture, as claimed.

Applicants argue they have amended the independent claims 1 and 31 to explicitly recite that the claimed human aneuploid stem cell culture has a majority of cells with a stable abnormal karyotype that comprises a trisomy selected from the narrowed group consisting essentially of sex chromosome X, autosomal chromosome 12, autosomal chromosome 17, and combinations thereof, and wherein the majority of cells of the claimed human aneuploid stem cell culture do not express SSEA1, but do express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80, and nestin, with

support in paragraphs [021], [052], [053], and Example 19. Applicants' arguments have been fully considered, but are not found persuasive.

In response, it is noted that no such support is evident in Applicants' disclosure. The cited sections of the specifications are completely silent on the identification of any cell surface markers, or the association of said markers with the various combinations of karyotypic abnormalities instantly claimed.

Thus, the rejection is maintained for reasons of record, and the preceding commentary.

New Claim Rejections - 35 USC § 112- New Matter

Applicants' claim amendments have necessitated the following new ground of rejection.

Claims 1, 2, 4-7, 31 and 75-79 are newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art (hereafter the Artisan), that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR §1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claims 1, 4, 7, 31 and 79 have been amended to recite human aneuploid embryonic stem cell cultures, wherein a majority of cells have a stable abnormal karyotype that comprises trisomy selected from the group consisting of a sex chromosome X, autosomal chromosome 12, autosomal chromosome 17 and combination thereof, and wherein the majority of cells of the culture do not express SSEA1, but express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin substantially uniformly.

Applicants state that no new matter has been presented in the amendment, and support may be found in paragraphs [021], [052], [053], [0211] and [0212]. Such is not found persuasive, because the specification fails to disclose either explicitly or implicitly, the characterization of any cultured aneuploid embryonic stem cell culture wherein a majority of cells have a stable karyotype that comprises a trisomy of sex chromosome X, automosomal chromosome 12, autosomal chromosome 17 and combinations thereof.

With respect to a stable abnormal karyotype, paragraphs [021] and [052] indicate that the cell culture has been dissociated to an essentially single cell culture, thus resulting in a cell line. Therefore it is not possible for a single cell culture to comprise a majority of cells that can have trisomies in either chromosome X, 12 or 17, or combinations thereof, as a single cell line is necessarily not a mixed cell culture of different genotypes.

With respect to the trisomy of a sex chromosome X, the disclosure is completely silent. As evidenced by paragraph [021], the abnormal karyotype comprises an additional sex chromosome (i.e. XXY or XYY); and in another embodiment, the karyotype comprises two X chromosomes and one Y chromosome (i.e. XXY). Further, none of the karyotypes disclosed in the table in paragraph [0212] contain a trisomy of the X chromosome.

As no aneuploid cells harboring the instantly claimed trisomies are apparent from Applicants' disclosure, the claimed cells cannot each be positive for the combination of SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin; and negative for SSEA1. However, the instant specification is silent on which specific autosomal abnormality corresponds to the specific combination of markers claimed. The specification is therefore silent on establishing a clear nexus between a particular karyotypic aneuploidy and the expression pattern of the cell surface markers claimed. As already noted, Applicants' specification is further devoid of the characterization of any aneuploid cells having an abnormal karyotype of trisomy of a sex chromosome X.

Thus, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of any of numerous human aneuploid stem cells that regardless of their karyotypic abnormality, express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin, either as an individual cell line or as a majority of cells in a mixed stem cell culture, as claimed.

MPEP 2163.06 notes: "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

This is a new matter rejection.

Response and Maintained Claim Rejections - 35 USC § 112-Scope of Enablement

Claim 1, 2, 4-7, 31 and 75-79 stand rejected under 35 U.S.C. 112, first paragraph, in modified form, as failing to comply with the enablement requirement. Applicants' cancellation of claims 8, 9, 80 and 81 renders their rejection moot. The rejection set forth on pp. 4-6 the previous Office action dated September 19, 2008 is maintained for reasons of record.

The enabled scope previously indicated is for the human aneuploid embryonic stem cell line BG01V derived from human ES cell line BG01, deposited as ATCC No. SCRC-2002.

The previous Office action indicated that the instant claims are directed to any human aneuploid embryonic stem cell having the particular cell surface marker profile of SSEA1$^-$, SSEA3$^+$, SSEA4$^+$, Oct-4$^+$, Tra-1-80$^+$/81$^+$ and nestin$^+$. However, Example 11 of the instant specification discloses that sorted HESCs were positive for the combination of SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin; and negative for SSEA1 (paragraph [0176], p. 65). Example 19 describes various abnormal karyotypes for hESC BG01-derived cell lines, that include trisomies 1, 7, 8, 12, 14 and 17 and other mixed karyotypes (paragraph [0212], p. 78). However, the instant specification is silent on which specific autosomal abnormality corresponds to the specific combination of markers claimed. The specification is therefore silent on establishing a clear nexus between a particular karyotypic aneuploidy and the expression pattern of the cell surface markers claimed. Moreover, the instant specification refers to Tra-1-80 as a defining marker of the instantly claimed cells throughout, but Example 11, teaches that the sorted hESCs were Tra-1-81$^+$. Therefore, a person of skill in the art would not be able to resolve the inconsistency, without further undue experimentation.

The post-filing evidence provided Applicants demonstrates the use of the BG01V cell line in various research applications, but additionally presents conflicting results with respect to this cell line. For example, Example B, from Invitrogen characterizes the cell line as having an abnormal karyotype 48XY/12+/17+. By contrast, Exhibit F, Zeng et al. characterized the cell line's karyotype as 49XXY, 12+,17+. The Exhibits additionally fail to ascribe the instantly claimed cell surface marker profile to the BG01V cell line. The instant claims encompass numerous karyotypically distinct cells derived from any of numerous human ES cell sources that all exhibit a specific cell surface marker signature or profile. Such is inconsistent with the teachings of both the instant specification and those of the prior art. Applicants' assertion that

any abnormal ES cell having any of numerous possible aneuploidies would at once be SSEA1$^-$, SSEA3$^+$, SSEA4$^+$, Oct-4$^+$, Tra-1-80$^+$/81$^+$ and nestin$^+$, and exhibit a phenotype identical to that of BG01V to allow a similar use, is unsubstantiated and would require further undue experimentation to elucidate.

Applicants traverse the rejection, arguing that claims 1 and 31 have been amended to recite a human aneuploid embryonic stem cell culture with a stable abnormal karyotype comprising a narrowed trisomy selected from the group consisting essentially of a sex chromosome X, and autosomal chromosomes 12 and 17, and combinations thereof; and enabled for a stable human aneuploid embryonic stem cell culture, comprising a cell with a stable abnormal karyotype that is selected from trisomies of XXY, +12, +17, or combinations thereof.

Applicants' arguments have fully considered but are not found persuasive. Applicants should note that an XXY karyotype is not analogous to a trisomy of sex chromosome X (i.e. XXX). The instant specification remains silent with respect to a trisomy of sex chromosome X, or each possible combination of the various trisomies instantly claimed. Thus, the specification is further devoid to associating the combined cell surface profile claimed with each of the possible karyotypic combinations, that are further required to be stable.

Applicants have been non-responsive to the issues previously raised regarding the Tra-1-80$^+$/81$^+$ markers, and the different karyotypes for the BG01V cell line.

Therefore, the rejection is maintained for reasons of record and the foregoing discussion.

Maintained & Withdrawn Claim Rejections - 35 USC § 102

Claims 1, 2, 5, 6, 31 and 75, 77 and 78 stand rejected under 35 U.S.C. 102(a) as being anticipated by Draper et al. (Nature Biotech. 22(1):53-54; published online Dec. 7, 2003), as evidenced by Mitalipova et al. (U.S. Patent Publication No.: 2005/0037488; effective filing date Aug. 6, 2001) and Nakayama et al. (U.S. Patent Publication No.: 2005/0221479; effective filing date June 23, 2003). Applicants' cancellation of claims 8 and 9 renders their rejections moot. In view of Applicants' amendments requiring a trisomy of sex chromosome X, the rejection of claims 4, 7, 76 and 79 is hereby withdrawn. The rejection set forth on pp. 6-9 of the previous Office action dated September 19, 2008 is maintained for claims 1, 2, 5, 6, 31 and 75, 77 and 78

for reasons of record.

The previous rejection is reiterated as follows:

Example 19 of the instant specification discloses that the cells showed abnormal karyotypes only following 32 or more passages, and included various autosomal trisomies. No such disclosure is present in the provisional Application 60/459,090. Thus, an artisan of skill would not be apprised of cellular aneuploidy as a result of specific passage number and conditions, or the nature of said aneuploidy, and would therefore not recognize that Applicants had possession of cells carrying specific karyotype abnormalities that included autosomal trisomies of chromosomes 1, 7, 8, 12, 14 and 17, as instantly claimed, that further do not express SSEA1, but express SSEA3, SSEA4, Oct4, Tra-1-60, Tra-1-80 and nestin, from the disclosure of the '090 Application. Therefore, the effective filing date of the instant claims is the filing date of PCT/US04/10121, filed 3/31/2004.

The rejection is applicable to the extent that the instant claims are enabled for a human aneuploid embryonic stem cell culture, comprising a cell with an abnormal karyotype that is either trisomy 12 or 17, or both.

The instant claims encompass cells expressing nestin, that appear to be at least partially differentiated along the neuronal path in embryoid bodies. Base claim 31 is drawn to a human aneuploid embryonic stem cell produced by antibody selection and maintenance in culture; and is thus a product by process claim.

MPEP 2112.01 states: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)." MPEP 2113 further states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Draper et al. teach the recurrent gain of chromosomes 17 and 12 in cultured human embryonic stem cells, wherein the cells retained an undifferentiated phenotype, were surface positive for SSEA3, Tra-1-60 and Oct4, and retained an ability to differentiate in culture (Title and first column, p. 53). With respect to the surface markers SSEA1$^-$, SSEA4$^+$, Tra-1-80$^+$/81$^+$ and nestin$^+$, it should be noted that these limitations would be pertinent should evidence be provided that the instantly claimed stem cells are structurally distinct from those disclosed by Draper et al. While Draper et al. did not test their aneuploid cells for the SSEA1$^-$, SSEA4$^+$, Tra-1-80$^+$ and nestin surface marker, such would be an inherent property of their stem cells, and the existence of these cell surface marker was known in the prior art, as evidenced by Mitalipova et al. who teach human ES cells staining positively for OCT-4 (FIG. 4A), Tra-1-60 (FIG. 4C), SSEA-3 (FIG. 4E), and SSEA4, (FIG. 4H); and negative for SSEA1 (FIG. 4J) cell surface markers (paragraph [0036]); and that known markers of pluripotent ES cells include stage specific embryonic antigen TRA-1-81 (paragraph [0090]). The neural marker nestin is taught by Nakayama et al. in differentiating stem cells (paragraph [0217]).

"When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or *In re Best*, 195 USPQ 430, 433 (CCPA 1997). As stated in MPEP 2112: The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Moreover, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

When the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102; or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

The examiner further maintains that the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of factual evidence to the contrary, the burden is upon the applicant to prove that the claimed products are **functionally different** than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips,* 28 USPQ 1302, 1303 (BPAI 1993), *In re Best,* 562, F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray,* 10 USPQ2d 1922, 1923 (BPAI 1989). The claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977); *In re Spada,* 15 USPQ2d 1655, Federal Circuit, 1990. See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore by teaching all the limitations of the claims Draper et al. anticipate the instant invention as claimed.

Response to Arguments

Applicants traverse the rejection arguing that Draper et al. do not describe a stable aneuploid cell line. Draper et al. describe that, with each increasing number of cell passages, the H7 and H14 cell lines have a corresponding sporadic increase in the prevalence of trisomy 12 and/or 17, e.g., 76 to 95%; or a gain of chromosome 12 in a subpopulation of cells. Further arguing that Draper et al. also describe various aneuploid cells in Table 1, with chromosome

changes in chromosomes 12 and/or t7, but it is clear that the chromosome changes in that report were not stable, thus not producing the human aneuploid stem cells with a "stable abnormal karyotype" of the claimed invention. Further, the chromosome stability (or instability) of those cell cultures was not dependent on the passage number since H14 was taken out to 41 passages and the H 1.1A and H 1.1B were taken out to passage 71.

Applicants' arguments have been fully considered, but are not found persuasive. In response, it should be noted that the stability that is applicable to the instant claims is for that of trisomies 12 or 17. And in this regard, Draper et al. do not teach that once a trisomy 12 or trisomy 17 is established in a cell, that it is unstable or lost. Applicants should note that the rejection over the prior art is applicable only to the extent that the instant claims are enabled.

Further, with regard to increasing karyotypic abnormalities, it is clear that Draper et al. are describing derivatives from a subline H7.S6 having trisomy in 17q or trisomy 12, by passage 60, and additionally a separate line H7.S14, that eventually resulted in 95% of the cells having trisomy 17. The resulting cell line having 95% trisomy 17 is not disclosed as unstable for the trisomy. As draper does not describe further passaging of the resulting cell line, Applicants' arguments with regards to the stability of the BG01V line are not germane. Thus, any karyotypic instability is relevant to the starting population of cells, that is also an inherent property of Applicants' starting cell population. Hence, Applicants' cells as claimed do not appear to be patentably distinct from those described by Draper et al.

Conclusion

Claims 1, 2, 4-7, 31 and 75-79 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The claims are drawn to the same invention claimed earlier in the application and would have been finally rejected on the grounds and art of record in the next Office Action if they had been entered earlier in the application. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR§1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Primary Examiner, Art Unit 1633